In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 22-99V

BARBARA SCIORTINO,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: July 24, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Michael G. McLaren, Black McLaren, et al., PC, Memphis, TN, for Petitioner.

Parissa Tabassian, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On February 1, 2022, Barbara Sciortino filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. §§ 300aa-1 et seq. ("Vaccine Act").[2] Petitioner alleges that an influenza ("flu") vaccine she received on October 30, 2019, caused her to suffer polymyalgia rheumatica ("PMR"). Petition at 1.

After review of the filed record exhibits, expert reports, and the parties' briefs, I hereby deny entitlement. It is not preponderantly likely that the flu vaccine can cause PMR. Theories comparable to what is advanced in this case have been repeatedly rejected in prior reasoned decisions, and no more recent scientific/medical evidence has been offered herein to suggest revisiting this rejected causation theory.

[1] "Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id."*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

On October 30, 2019, Ms. Sciortino (then eighty-two years old) received the flu vaccine. Ex. 1 at 5. There is nothing in the filed records suggesting Petitioner experienced an immediate and/or unusual reaction. However, on December 2, 2019, Petitioner contacted an urgent care facility by phone, complaining that she had been experiencing full body pain since the day after vaccination a month before. Ex. 2 at 8.

Petitioner was advised to visit urgent care in person the next day (although it does not appear from the record she did so). Ex. 2 at 8. Instead, on December 12, 2019 (over a week after the urgent care call), Petitioner saw internist Dr. Uche Foluke complaining of body aches all over, especially in her neck, shoulders, and knees, and difficulty walking since receiving the flu vaccine. Ex. 3 at 37–38. Dr. Foluke's assessment was body aches and "reaction to shot." *Id*. at 37. Then, two days later (December 14, 2019), she went to the emergency department of Spring Valley Hospital, reporting worsening joint pain and difficulty walking since receiving the flu vaccine. Ex. 4 at 11–16. Petitioner also described generalized descending arthralgias and constant, aching pain. Id. A physical examination performed at this time revealed a mild shuffling gait, and Petitioner was assessed with having arthralgias and chronic anemia, and prescribed medication for treatment of symptoms. *Id*. at 16.

The following month, Petitioner saw primary care provider Dr. Alexander Noche, reporting pain in multiple joints, in her right arm, and in both thighs, and requesting a refill of prednisone, which had effectively helped her pain. Ex. 3 at 34–35. Dr. Noche's assessed Petitioner with arthralgias of multiple joints and hypertension, and he prescribed a steroid dosepak. *Id.* On January 8, 2020, she followed up with Dr. Foluke. Ex. 3 at 30–32. Dr. Foluke noted Petitioner's symptoms, which were ongoing, had an unclear etiology, assessed her with arthralgias of multiple joints, and ordered updated laboratory studies. *Id.*

On January 15, 2020 (now approximately ten weeks post-vaccination), Ms. Sciortino returned to Dr. Foluke. The lab results indicated a positive ANA IFA test[3] plus slightly low hemoglobin levels, along with an elevated inflammation biomarker. Ex. 3 at 27–29, 42–49. Dr. Foluke's assessment remained largely the same, but it was recommended that Petitioner see a rheumatologist. *Id*. at 27–29. Petitioner did so later that month, visiting Dr. William Kim on January 28, 2020. Ex. 6 at 28–29. She again maintained that her weakness and pain had begun close in time to vaccination, and that oral steroid treatments had yielded some improvement. *Id*. at 28. Dr. Kim assessed Petitioner with PMR, with symptom onset after the flu vaccine, plus degenerative joint disease, and prescribed an oral steroid. *Id*. at 28–29.

[3] "The antinuclear antibody using an immunofluorescence assay ("ANA IFA") is a first line screen for detecting the presence of up to approximately 150 autoantibodies in various autoimmune diseases. A positive ANA IFA result is suggestive of autoimmune disease." Respondent's Brief at 3, filed on January 17, 2024 (ECF No. 25).

Thereafter, Petitioner continued to follow up with Dr. Kim throughout 2020. Although some of her symptoms varied, the PMR assessment remained the same. *See,* e.g., Ex. 3 at 26–27 (February 2020 visit), 24–25 (March 2020), and 8–23 (visits into December 2020). Primary care providers reached a consistent diagnosis. *Id.* at 12–19. No records for subsequent timeframes were filed.

II. Expert Opinions

A. *Petitioner's Expert – M. Eric Gershwin, M.D.*

Dr. Gershwin prepared two expert reports in this matter. *See* Report, dated February 15, 2023 (ECF No. 21-1) ("First Gershwin Rep."); Report, dated August 28, 2023 (ECF No. 23-1) ("Second Gershwin Rep."). Dr. Gershwin maintains that Petitioner's PMR was caused by the flu vaccine.

Prior to his retirement, Dr. Gershwin was a Distinguished Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology at the University of California Davis School of Medicine. First Gershwin Rep. at 2. He also served as the Chief of the same division for nearly twenty years. *Id*. Dr. Gershwin received his medical degree from Stanford University, and completed his residency at Tufts-New England Medical Center. *Id.* He is certified by the American Board of Internal Medicine in Rheumatology, and by the American Board of Allergy and Clinical Immunology. *Id*. He serves as an editor for several autoimmunity and allergy journals, and has co-authored over a thousand articles. *Id.*

In his first written report, Dr. Gershwin began with a summary of Petitioner's medical history. First Gershwin Rep. at 1–2. He then briefly addressed PMR, characterizing it as an "inflammatory disease" that is "closely related to temporal arteritis." *Id.* at 3. It features bilateral aching plus stiffness (most typically in the neck, arms, shoulders, or thighs), has a higher incidence in individuals over the age of 50 (whose immune response is often less robust), and is often responsive to prednisone. *Id.* at 3, 4.

Dr. Gershwin proposed that PMR could be mediated by an innate immune response involving initial cytokine production. First Gershwin Rep. at 3, 4. His causation theory relied on comparing PMR to giant cell arteritis/temporal arteritis, and he block-quoted an article proposing a mechanism involving T-helper cells that can play a role in encouraging B-cell antibody production. *Id.;* M. Gonzalez-Gay et al., *Giant Cell Arteritis and Polymyalgia Rheumatica: An Update*, 17 Curr. Rheumatol. Rep. 6 (2015), filed on July 11, 2023 as Ex. A-2 (ECF No. 22-3). PMR, he maintained, involved "an enhanced/increased pro-inflammatory response," likely amplified by individual susceptibility and age (although the impact of vaccination in such an environment was not likely measurable by epidemiologic studies). First Gershwin Rep. at 4.

In support of his opinion, Dr. Gershwin noted the existence of case reports associating PMR with the flu vaccine. First Gershwin Rep. at 5; M. Bassendine & S. Bridge, *Relapse of Polymyalgia Rheumatica Following Adjuvanted Influenza Vaccine: A Case-Based Review*, 7 Eur. J. Rheumatol. 37

(2020), filed on March 1, 2023 as Ex. 30 (ECF No. 21-17) ("Bassendine & Bridge"); P. Felicetti et al., *Spontaneous Reports of Vasculitis as an Adverse Event Following Immunization: A Descriptive Analysis Across Three International Databases*, 34 Vaccine 6634 (2016), filed on March 1, 2023 as Ex. 29 (ECF No. 21-16) ("Felicetti"). He also noted that vaccines are generally known to cause upregulation of cytokines. Thus, it was in his determination likely that the flu vaccine could cause PMR. First Gershwin Rep. at 5.

Dr. Gershwin's second report was considerably longer than the first, and vigorously endeavored to rebut each point made by Respondent's expert, Dr. Matloubian, in reaction to Dr. Gershwin's earlier report. *See generally* Second Gershwin Rep. at 1–18. Dr. Gershwin generally emphasized his opinion that vaccines could cause PMR by "dysregulating immunity" in an older person like the Petitioner, who also likely had some underlying, if unidentified, susceptibility. Second Gershwin Rep. at 1. Thus, it did not matter that a specific infectious/antigenic trigger had ever been identified for PMR (although Dr. Gershwin emphasized that evidence he had offered did link vaccines to PMR). *Id.* Nor was Petitioner's prior tolerance of vaccination without development of an autoimmune injury evidence that she could not develop a vaccine-instigated injury later. *Id.* at 2.

Regarding specific aspects of his proposed theory, Dr. Gershwin maintained that even if cytokine production occurred during the initial, innate phase of the immune response, their impact on the subsequent immune process could persist even after their production ended. Second Gershwin Rep. at 3. In support (and somewhat dovetailing with arguments about the reasonableness of a short onset that are less relevant to my determination), Dr. Gershwin embarked on a science-thick evaluation of the theorized pathophysiology of PMR, highlighting the role of cytokines in the process. *Id.* at 4–6, 9–12. He also noted the extent to which cytokine dysregulation might be a problem for the elderly, or those who otherwise were susceptible (as was assumed to be the case for Petitioner). *Id.* at 7–8, 13.

At bottom, Dr. Gershwin contested Dr. Matloubian's unwillingness to agree that cytokines likely had *some* association with PMR's pathology. Second Gershwin Rep. at 17. And Dr. Gershwin continued to maintain that Petitioner's age, plus some unidentified susceptibility, likely impacted the effect of the vaccine she received. *Id.* at 17–18.

B. *Respondent's Expert – Mehrdad Matloubian, M.D., Ph.D.*

Dr. Matloubian prepared one written report for Respondent. Report, dated June 23, 2023, filed as Ex. A (ECF No. 22-1) ("Matloubian Rep."). Dr. Matloubian denied the flu vaccine can cause PMR.[4]

Dr. Matloubian received his B.S., M.D., and Ph.D. (specializing in immunology and virology) from the University of California, Los Angeles. Matloubian CV, filed on July 11, 2023 as Ex. A-17 (ECF No. 22-18) ("Matloubian CV"); Matloubian Rep. at 1. He completed a residency in Medicine at

[4] Because this case turns on the "can cause" prong, I do not include a summary of Dr. Matloubian's arguments about the reasonableness of the timeframe in which Petitioner's PMR began. Matloubian Rep. at 16.

the University of California, San Francisco ("UCSF"), followed by a fellowship in rheumatology at the same facility. Matloubian CV at 1. He has served as an associate professor of Medicine at UCSF since 2001. Matloubian CV at 2. In his research, Dr. Matloubian focuses on innate and adaptive immune responses to viral infections, and he has published numerous articles in reputable medical journals on issues in this field. *Id.* at 8, 10–15; Matloubian Rep. at 1. In addition to teaching and research work, he also serves as associate director of the UCSF Molecular Medicine Consult Service, which is a recently-established hospital service involving both clinicians and research scientists, who work together to treat patients with a variety of unusual disorders. Matloubian CV at 3. Additionally, Dr. Matloubian has spent one month per year as an attending physician on the UCSF Inpatient Rheumatology Consult Service since 2001. *Id.*

Like Dr. Gershwin, Dr. Matloubian's report provided an overview of Petitioner's relevant medical history, and he allowed that her presentation and lab work were all at least "suggestive of PMR" as the appropriate diagnosis. Matloubian Rep. at 1–4, 8. But Dr. Matloubian flatly rejected the possibility that the flu vaccine could be causal of it. He maintained that medical science's understanding of PMR's pathogenesis remained "at a very primitive level," at least in comparison of other known autoimmune conditions, and he deemed immune-related findings specific to PMR to be more "descriptive" than mechanistically explanatory. *Id.* at 6. He highlighted the fact that no known autoantibody had been identified as causal of PMR, nor was there yet an identified target antigen in the body that might be the initial situs for disease attack. *Id.* At best, PMR likely involved a combination of B cells and T-helper cells, resulting in autoantibody production leading to self-attack for genetically-susceptible individuals—but with no known environmental trigger. *Id.* at 6–7.

Dr. Matloubian next endeavored to rebut each aspect of Dr. Gershwin's causation theory. Dr. Gershwin, for example, proposed that a pro-inflammatory setting, featuring cytokine production, was attacking muscle, leading to PMR, when in fact science deemed "proximal articular and periarticular structures (bursae and tendons)" to be the impacted self-tissues in PMR. Matloubian Rep. at 9. Dr. Gershwin also seemed to conflate an inflammatory *environment* attributable to a preexisting infectious cause and the presence of that inflammation, assuming that it was both vaccine-caused and causal of PMR. *Id.* And the specific cytokines Dr. Gershwin proposed as causal, like IL-6, were not known generally to cause other autoimmune diseases even if found *in association* with such conditions (and their presence could simply be a by-product of the ongoing disease pathogenesis rather than an instigating factor). *Id.* at 10.

Another aspect of Dr. Gershwin's opinion criticized by Dr. Matloubian was the contention that PMR was the result of an innate immune-driven response. Matloubian Rep. at 11–12. He noted that Dr. Gershwin was both suggesting that the disease was caused by a "cytokine-driven process"—but also that it was the product of antibody attack responding to self-antigens (even though no target or initiating foreign antigen had been identified, by science or by Dr. Gershwin), which would implicate the *adaptive*, secondary leg of the immune response. *Id.* at 12. Indeed, T-cell involvement in PMR's pathogenesis would more likely occur as part of the adaptive response. *Id.* Thus, the proposed theory

essentially involved all aspects of the immune response, but without a showing that the initial impact of vaccination could credibly start the process (let alone impact it at multiple stages).

In addition, Dr. Matloubian maintained that Dr. Gershwin had not identified (other than via case reports observing a temporal association with vaccination) reliable medical literature establishing a possible environmental trigger (and this was not a situation in which a viral or bacterial infection having some connection to a vaccine was a putative cause). Matloubian Rep. at 9. Case reports, or passive surveillance data, were not especially probative of causation in Dr. Matloubian's view. *Id.* at 12. At the same time, some larger-scale epidemiologic studies (albeit involving vasculitis as opposed to PMR directly) were unsupportive of a vaccine association. C. Bonetto et al., *Vasculitis as an Adverse Event Following Immunization- Systematic Literature Review*, 34 Vaccine 6641 (2016), filed on July 11, 2023 as Ex. A-11 (ECF No. 22-12). The same findings were reached in an article Dr. Gershwin himself had cited. Matloubian Rep. at 13; Felicetti at 6.

Studies more specific to PMR were not particularly reliable or persuasive, in Dr. Matloubian's reading. One only identified two possible individuals (out of 12 studied) who had experienced PMR or GCA after vaccination, and its authors seemed to favor an adjuvant as contributing to the disease (even though the version of the flu vaccine at issue in this case *contains no adjuvant*). Matloubian Rep. at 13–14; E. Lionzon et al., *Giant Cell Arteritis or Polymyalgia Rheumatica After Influenza Vaccination: A Study of 12 Patients and a Literature Review*, 20 Autoimmunity Reviews 1 (2021), filed on March 1, 2023 as Ex. 34 (ECF No. 21-21).[5] Petitioner had also received vaccines before—so were she uniquely susceptible to PMR for some unknown underlying genetic reason, she likely should have experienced a disease process before, but had not. *Id.* at 10. And receipt of the flu vaccine otherwise was so common that coincidence alone likely explained the vast majority of situations where PMR (or some comparable condition) occurred after a vaccination. *Id.* at 15.

III. Procedural History

This case was initiated in the winter of 2022, and assigned to my docket that spring after completion of "pre-assignment review" (performed on newly-filed cases to ensure that sufficient documents regarding the claim have been filed). Respondent's Rule 4(c) Report contesting entitlement to compensation was filed in August 2022 (ECF No. 15), and thereafter the parties filed the aforementioned expert reports through late summer 2023. I subsequently set a schedule for briefing the matter via ruling on the record, and each side offered briefs in support of their respective positions. *See* Petitioner's Motion for Ruling on the Record, dated November 16, 2023 (ECF No. 24) ("Br.");

[5] In addition, as Dr. Matloubian noted, Lionzon's authors seemed to embrace the "ASIA theory" (meaning "autoimmune syndrome induced by adjuvants") as disease-causing—a theory Dr. Matloubian correctly noted to have been "discredited." Matloubian Rep. at 14; *see also D'Angiolini v. Sec'y of Health & Human Servs.*, No. 99-578V, 2014 WL 1678145 (Fed. Cl. Spec. Mstr. Mar. 27, 2014) (determining that the ASIA theory did not meet the minimum threshold for reliability and thus could not be a reliable basis for compensation), *mot. for review den'd*, 122 Fed.Cl. 86 (July 2, 2015), *aff'd*, 645 Fed. Appx. 1002 (Fed. Cir. 2016); *Rowan v. Sec'y of Health & Human Servs.*, No. 10-272V, 2014 WL 7465661 (Fed. Cl. Spec. Mstr. Dec. 8, 2014) (rejecting the ASIA theory, as it is not a proven theory and the mechanism whereby adjuvants could cause autoimmune illness is not known), *mot. for review den'd*, 2015 WL 3562409 (Fed. Cl. June 9, 2015).

Respondent's Brief, dated January 17, 2024 (ECF No. 25) ("Opp."); Petitioner's Reply, dated February 5, 2024 (ECF No. 26) ("Reply"). The matter is now ripe for resolution.

IV. Parties' Arguments

Petitioner

Petitioner maintains that she can preponderantly establish that the flu vaccine she received was a "but for" cause of her PMR (a diagnosis that is not disputed). Br. at 4, 6. Among other things, she contends she satisfies the first prong of the test for entitlement created by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005)—sometimes referred to as the "can cause" prong. Br. at 5–7.

Her theory, as propounded by Dr. Gershwin, is that autoimmune diseases can be triggered by environmental factors in susceptible individuals—but that scientific studies are more often than not insufficiently sensitive to detect "such admittedly rare reactions." Br. at 6. Here, Dr. Gershwin has offered a reasonable and persuasive theory, in which cytokine production—occurring during the innate immune response phase, and instigated by receipt of a vaccine—induces PMR, a contention Petitioner argues is supported by literature filed in this case. *Id.* at 7; Felicetti at 1–4. This occurs due to immune "dysregulation"—and the cytokines have been established to play some role in PMR's pathogenesis, despite Dr. Matloubian's denials. Br. at 7.

Petitioner's reply was longer than her initial brief, and most of it expands on why she maintains she has demonstrated that the flu vaccine "can cause" PMR. Reply at 4–9. She argues that she cannot be required to offer a definite, infectious trigger for PMR, especially given the paucity of epidemiologic evidence relevant to the matter (and its inability otherwise to detect rare events). *Id.* at 4. At the same time, however, she contends that even if PMR *itself* is not uncommon, this does not preclude the possibility of a rare causal event, like a vaccination. *Id.* at 5. Further, the impact of cytokines on the immune system would likely persist after vaccination (and it is unfair to require Petitioner to prove this in connection with PMR specifically, given the number of other known autoimmune conditions in which multiple environmental triggers are possible). *Id.* at 6. Petitioner stresses that Dr. Gershwin's theory—"that the innate immune response does begin the process of driving an antigen response"—is consistent with how the overall immune response, including both its innate and adaptive "legs," are understood to function. *Id.* at 7. And Petitioner notes the value of case reports, passive surveillance data, and other literature offered to support a vaccine association. *Id.* at 7–8.

Respondent

Respondent denies that Petitioner has met her burden of proof, and in so arguing devotes most of his brief to challenging her success in satisfying the first *Althen* prong. *See generally* Opp. at 6–14. He notes that even though PMR is not particularly rare, medical science has not identified an infectious etiology for it (despite looking at the issue)—undermining the possibility that a vaccine could be causal

as well, or even a trigger in the right context. *Id.* at 7. In fact, since PMR is not rare, as Dr. Matloubian noted, the fact that large numbers of individuals receive the flu vaccine annually means that coincidence alone likely explains instances in which PMR temporally follows vaccination. *Id.* at 8.

The specific components of Dr. Gershwin's theory, moreover, were deemed by Respondent to be unreliable or inadequately-supported. First, Respondent repeated Dr. Matloubian's argument that (a) vaccine-induced cytokine production has not been demonstrated to instigate PMR (and the presence of those cytokines may simply be a by-product of the subsequent disease process), and (b) no other vaccine-caused antigenic trigger was identified by Dr. Gershwin. Opp. at 8–9. Second, Respondent contended that Dr. Gershwin's theory largely posited PMR to be an innate immune response-driven disease, while at the same time admitting an antigenic stimuli was necessary (which would involve the secondary, adaptive response)—but without his identifying what that antigen, or self-antigen target, would be. *Id.* at 9–10.

In addition, the medical/scientific support for the theory came from either VAERS data[6] or case reports—evidence not typically afforded much weight in Program cases. Opp. at 11; *see also* Opp. at 11 n.5. Even the more recently-published item cited by Dr. Gershwin, Felicetti, specifically acknowledged that it could not opine on causality. Felicetti at 12. And other items of literature involved GCA—not PMR—and were distinguishable. Opp. at 12 (*referencing* Liozon). Otherwise, Petitioner could identify no reliable independent evidence suggesting an association between the flu vaccine and PMR—at most relying on evidence specific to vasculitis, but which in fact did *not* observe a vaccine association. *Id.* at 12–13. Petitioner's theory was simply too speculative and lacking foundation to be deemed reliable for Program purposes. *Id.* at 13–14.

V. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly*, 592 F.3d

[6] "VAERS," or the Vaccine Adverse Event Reporting System, is a passive surveillance system maintained by the Center for Disease Control, in which anyone may file a report alleging that a vaccine caused a particular injury, illness, or death. VAERS exists to prompt further scientific investigation into potentially dangerous vaccines. Thus, and as discussed by other special masters, the data provided by VAERS does not illustrate a causal connection between a vaccine and a specific injury. *See*, e.g., *Tompkins v. Sec'y of Health & Human Servs.*, No. 10-261V, 2013 WL 3498652, at *9 n.25 (Fed. Cl. Spec. Mstr. June 21, 2013), *mot. for review den'd*, 117 Fed. Cl. 713 (2014). VAERS reports are informal and unverified, and should not be confused with formal case reports in medical literature (which are also given less weight as proof of causation). *Tompkins,* 2013 WL 3498652, at *9 n.26. For these reasons, other special masters have consistently declined to rely on VAERS data as probative with regard to vaccine causation. *See, e.g., Analla v. Sec'y of Health & Human Servs.,* 70 Fed. Cl. 552, 558 (2006); *Ryman v. Sec'y of Health & Human Servs.*, 65 Fed. Cl. 35, 39–40 (2005).

at 1321; *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[7] There is no Table claim for PMR as an injury associated with *any* covered vaccine, so Petitioner can only advance a causation-in-fact claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface*, 165 F.3d at 1352–53); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence

[7] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent") (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd,* 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29,

2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir.

1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments

as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Program Treatment of PMR as Vaccine Injury

PMR has not generally been deemed a likely vaccine injury—as demonstrated by a number of persuasive prior reasoned decisions. *See generally Thompson v. Sec'y of Health & Hum. Servs.,* No. 18-1217V, 2023 WL 9053982 (Fed. Cl. Spec. Mstr. Dec. 5, 2023) (SM Oler) (pneumococcal vaccine

not found causal of claimant's PMR); *Van Dycke v. Sec'y of Health & Hum. Servs.,* No. 18-106V, 2023 WL 4310701 (Fed. Cl. Spec. Mstr. June 7, 2023) (SM Dorsey) (Tdap vaccine not found causal of claimant's PMR); *Giesbrecht v. Sec'y of Health & Hum. Servs.,* No. 16-1338V, 2023 WL 2721578 (Fed. Cl. Spec. Mstr. March 30, 2023) (SM Moran) (flu vaccine not found causal of claimant's PMR); *Kelly v. Sec'y of Health & Hum. Servs.,* No. 17-1475V, 2022 WL 1781957 (Fed. Cl. Spec. Mstr. Oct. 12, 2022) (SM Horner) (flu vaccine not found causal of claimant's PMR); *Suliman v. Sec'y of Health & Hum. Servs.,* No. 13-993V, 2018 WL 6803697 (Fed. Cl. Spec. Mstr. Nov. 27, 2023) (SM Roth) (Tdap vaccine not found causal of claimant's PMR). All of these decisions provide persuasive, useful guidance for resolving this matter (as recognized by Respondent)[8]—and importantly, none were appealed.

The two most on-point determinations are *Giesbrecht* and *Kelly,* since both involved the flu vaccine, plus some of the same experts as in this case.[9] *Giesbrecht* (the more recent of the two decisions) admittedly turned in part on the special master's finding that the PMR diagnosis had not been substantiated. *Giesbrecht,* 2023 WL 2721578, at *5–7. However, that special master also determined that *Althen* prong one had not been satisfied. *Id.* at *7–8. In so doing, he rejected an opinion offered by Dr. Gershwin as (a) applying an autoimmune theory of causation to a disease not likely to have an autoimmune mechanism, and (b) unpersuasively relying on an innate, cytokine-driven response akin to what has been rejected in numerous prior matters—but which is expressly relied upon *in this case*. *Id.* at *7.[10] The special master also followed numerous prior cases involving claims that PMR was vaccine-caused, including *Suliman. Id.* at *8.

The *Kelly* petitioner's PMR diagnosis was not in dispute, but that claimant was nevertheless unsuccessful, with the special master finding that none of the three *Althen* prongs were established. *Kelly,* 2022 WL 1781957, at *8–12. In finding the "can cause" prong not preponderantly met, the special master faulted the theory's failure to identify target antigens for autoimmune attack, as well as the lack of evidence suggesting that PMR was autoimmune, that it could be instigated by a particular kind of autoantibody, or that it had *any* known external trigger. *Id.* at *9. The special master also deemed analogies to giant cell arteritis unpersuasive, and found case reports weak proof (especially to the extent they involved injuries other than PMR itself). *Id.* at 10–11.

Two of the other aforementioned cases involved different vaccines, but featured an expert opinion from Dr. Gershwin. *See,* e.g., *Thompson*, 2023 WL 9053982, at *5–7, 13–16 (pneumococcal vaccine); *Van Dycke*, 2023 WL 4310701, at *9–14, 22–27 (Tdap vaccine). Both have guidance value herein, even if the vaccines at issue were different (and *Thompson* featured *both* Drs. Gershwin and

[8] *See* Opp. at 14 n.6 (referencing *Van Dycke, Giesbrecht, Kelly,* and *Suliman*).

[9] Dr. Gershwin offered an opinion for the *Giesbrecht* petitioner, while Dr. Matloubian was Respondent's expert in *Kelly.*

[10] Respondent's brief in this case also cites *Giesbrecht* for this point, listing a large number of other Program decisions rejecting theories that rely on cytokine production instigated by vaccines as causal of autoimmune diseases. *See generally* Opp. at 9 n.4 (citations omitted).

Matloubian, as here). *Thompson* involved a theory of an aberrant, innate immune response to vaccination driven by cytokine production, akin to what was considered but rejected in *Giesbrecht. Thompson,* 2023 WL 9053982, at *13–14. Dr. Gershwin also in *Thompson* offered the Felicetti and Bassendine & Bridge papers.[11] Otherwise, *Thompson* noted no evidence that infections can trigger PMR (thus diminishing the possibility of a vaccine cause), and took into account the many reasoned cases rejecting theories that PMR is vaccine-caused. *Id.* at *16.

Van Dycke's analysis of the persuasiveness of Dr. Gershwin's theory was considerably more detailed. Like the other cases reviewed herein, it was noted in *Van Dycke* that Dr. Gershwin had failed to identify a specific causal antigen—and in this context, assumed a vaccine-instigated process without proposing molecular mimicry as the mechanism. *Van Dycke,* 2023 WL 43120701, at *22. Thus, he failed to explain what triggers the T cell activation involved in the putative disease process resulting in PMR. *Id.*

These cases do not compel or control the outcome herein. But they all provide reasoned grounds to be skeptical of claims that many covered vaccines can cause PMR—and especially where the same kinds of arguments were previously voiced but rejected after careful consideration.

II. Petitioner Has Not Carried Her Burden of Proof

As is well understood in the Program, the failure to establish even one of the three *Althen* prongs in the context of a causation-in-fact claim is sufficient basis for a claim's dismissal. *Dobrydnev v. Sec'y of Health & Hum. Servs.,* 566 Fed. Appx. 976, 980 (Fed. Cir. 2014). This case wholly turns on the first, "can cause" prong—and because I find it has not been preponderantly established, no discussion of Petitioner's success with respect to the other prongs is necessary.

Dr. Gershwin's theory largely mirrors what has been unsuccessfully advanced in prior cases involving PMR.[12] As before, he relies heavily on a cytokine-driven process that conflates innate and immune phases, but largely focusing on the vaccine's initial stimulation of cytokine production—but without a persuasive or reliable showing that this initial upregulation of cytokines is likely to instigate a

[11] See n5 for an explanation of the ASIA theory implicated in Bassendine & Bridge. As noted in *Thompson,* "[t]hese articles do not increase the persuasiveness of Dr. Gershwin's opinion. . . . Bassendine & Bridge similarly discuss[es] one case report involving the flu vaccine. While Felicetti does include some cases of vasculitis after a variety of vaccines, to include pneumococcal vaccine, the article is still a collection of case reports. While petitioners can present case reports in support of their causal theory, they are not an especially persuasive form of evidence." *Thompson v. Sec'y of Health & Hum. Servs.*, No. 18-1217V, 2023 WL 9053982, at *15 (Fed. Cl. Spec. Mstr. Dec. 5, 2023).

[12] *Giesbrecht,* for example, is the most recent case also involving the allegation that the flu vaccine caused PMR. But the first report prepared by Dr. Gershwin in *Giesbrecht* is not only largely identical to what was offered in this case, but features 13 of the same citations, with only a few more recently-published articles that could not have been filed at the time the *Giesbrecht* report was authored. *Compare* First Gershwin Rep. at 6-7 *with* Report, dated December 12, 2017 (ECF No. 17-2), filed in *Giesbrecht*. In addition, Dr. Gershwin responded with many of the same rebuttals to Dr. Matloubian's arguments in *Thompson* as he did in the case at hand, including emphasizing the susceptibility of elderly individuals to "age-dependent dysregulation of innate immunity." *Thompson*, 2023 WL 9053982 at *7; Second Gershwin Rep. at 7–8.

disease process that will involve many other aspects of the immune response. Dr. Gershwin cannot analogize to the wild flu virus as triggering PMR, has not identified an antigenic stimulus, and does not attempt to set forth a target self-antigen where an autoimmune attack resulting in PMR would occur. Otherwise, Dr. Gershwin's implication of IL-6 as a specific driver of PMR is unsupported, especially since (as Dr. Matloubian points out) it could be gleaned from the relevant studies that IL-6 is merely a *byproduct* of the disease process. First Gershwin Rep. at 4; Matloubian Rep. at 10.

Dr. Matloubian, by contrast, more convincingly and persuasively showed why it is unlikely the flu vaccine can cause PMR. He highlighted that the basic pathogenesis of PMR is still not well understood, and that no specific auto-antibody driver or target antigen has been identified for it. Further, Dr. Gershwin's theory confusingly focuses on a cytokine reaction occurring in the innate immune system, yet states that the reaction is antigen-driven (which would implicate the adaptive response)—thus leaving unanswered whether the pathogenic process resulting in PMR occurs mainly in one or the other. And vaccine causation for PMR is unsupported in the medical literature.

Overall, the causal deficiencies in the theory—previously identified by a majority of presently-serving special masters in several well-reasoned determinations—have not been overcome (or even addressed) by the version of the theory presented in this case. Many of these decisions were issued before principal briefing in this case, giving Petitioner ample opportunity to digest them and even propose why they are in error, or otherwise demonstrate how they failed to take into account evidence offered in this case but not previously considered. Yet she did not do so—and my own review of the record and the parties' briefs finds no grounds to deem an association between the flu vaccine and PMR likely, when so often that association has been persuasively rejected.

CONCLUSION

Preponderant evidence does not support Petitioner's causation theory. She is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[13]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[13] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.